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Dockets Management Branch (HFA-305)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 02857

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To Whom It May Concern,

March 19, 1999

I am a health professional and a lifelong celiac. Celiac Disease, as you may know, is a particularly troubling autoimmune disorder. A person with Celiac Disease (celiac) may be mis-diagnosed for many years, as the disease presents in such a variable manner. Once diagnosed, complete avoidance of certain prolamins, found in glutens, must be strictly adhered to in a celiac's diet.

The problem of ferreting out hidden glutens is a daily, full-time task for a celiac. One area of concern, among many, is the question of gluten-free medications. Many celiacs have relied upon Formulating Pharmacies for the safe preparation of many of their medication needs. The proposal to limit the interstate transfer of formulated medications would put celiacs at risk. Often there are no safe alternatives to be found in mainstream pharmaceutical offerings. In addition, many manufacturers use a variety of ingredients, based upon economic decisions and availability of raw materials. Thus a medication that is safe may in the next manufacturing lot be altered, rendering it unusable by a celiac.

There is evidence that ingestion of hidden glutens increases a celiacs likelihood of contracting lymphomas and intestinal cancers at a rate that far exceeds the non-celiac population.

Please consider this information as you weigh the merits and risks of implementing the proposed legislation.

Respectfully,

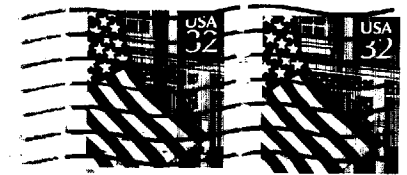


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